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(17614)

PATENT

REMARKS

Upon entry of this amendment, claims 1, 5-7, 9-11, 18-21 and 75-80 will be pending in this application. The amended claims and new claims are fully supported by the original claims and the specification at, for example, paragraphs [0010] to [0013], [0043], [0044], [0059], [0060] and [0062].

As a preliminary matter, Applicant acknowledges with thanks the withdrawal of the rejections under obviousness type double patenting, 35 U.S.C. 112 (first paragraph) and 35 U.S.C. 1102(b).

Fig. 2 is being objected to for a typographical error with respect to SEQ ID NO: 39. SEQ ID NO: Applicant is submitting under a separate cover a revised sequence listing and revised Fig. 2 to address this matter.

The amino acid and nucleotide sequences on pages 25, 26, 37 and 38 have been objected to for not identifying a SEQ ID NO. Applicant is submitting under a separate cover an amendment and a revised sequence listing to include SEQ ID NO's for the referenced sequences.

The Claims Are Definite

Claims 1, 5-7, 9-11, 18-21, 73 and 74 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for lacking "essential steps", i.e., "an effective amount of a glycosylated inactive botulinum toxin" and "the outcome of the treatment". The Office Action, at page 4.

With regards to the Office Action's requirement to recite the **"effective amount of a glycosylated inactive botulinum toxin"**, solely to facilitate prosecution, the claims have been amended to recite that the amount of a glycosylated inactive botulinum toxin administered is an amount of glycosylated inactive botulinum toxin sufficient to compete with an active botulinum toxin for binding to a cell surface receptor, an endosomal

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membrane, a SNAP-25 protein, a synaptobrevin (VAMP) or a syntaxin, to reduce the ability of the active botulinum toxin to intoxicate a neuron. For example, the present specification teaches that a glycosylated inactive botulinum toxin treats botulinum toxin intoxication by *competing* with the active botulinum toxin at the receptor sites. The Specification, at paragraph [0043]. Further, the specification teaches that the cell surface, endosomal membrane, SNAP-25 protein, synaptobrevin (VAMP) and syntaxin have receptor sites for a botulinum toxin to bind and to intoxicate a neuron. The Specification, paragraphs [0010] to [0013]. When the glycosylated inactive botulinum toxin competes with an active botulinum toxin at these receptor sites, the glycosylated inactive botulinum toxin reduces the ability of the active botulinum toxin to intoxicate the neuron. Thus, the "effective amount of a glycosylated inactive botulinum toxin" is now expressly recited in the claims.

With regards to the Office Action's requirement to recite the **"outcome of the treatment"**, solely to facilitated prosecution, Applicant has amended the claims to recite the phrase "thereby reducing the ability of the active botulinum toxin to intoxicate a neuron". Thus, the outcome of the treatment is now expressly recited in the claims.

In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,

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Date: January 20, 2006

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